

09/187661

NOVEL IGF-I COMPOSITION AND ITS USE
ABSTRACT OF THE DISCLOSURE

A highly concentrated, low salt-containing, biologically active syrup form of IGF-I or variant thereof and methods for its preparation are provided. This novel syrup form of IGF-I has an IGF-I concentration of at least about 250 mg/ml, a density of about 1.0 g/ml to about 1.2 g/ml, and a viscosity of about 13,000 centipoise (cps) to about 19,000 cps, as measured at ambient temperature (23°C). The IGF-I syrup is prepared by precipitating or partitioning IGF-I from solution, preferably by adjusting the solution pH or by use of a solubility enhancer to concentrate IGF-I in solution followed by removal of the solubility enhancer. The precipitated syrup is useful as a means of storing IGF-I in a stable form and as a means of preparing compositions comprising biologically active IGF-I. Pharmaceutical compositions and kits comprising this concentrated IGF-I syrup are provided. The precipitated IGF-I syrup, IGF-I reconstituted from the IGF-I syrup, pharmaceutical compositions, and kits are useful in IGF-I therapy directed to IGF-I-responsive conditions.

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